

## UNITED STATES PATENT AND TRADEMARK OFFICE



UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address CoMMISSENER OF PATENTS AND TRADEMARKS Woodmagton DC 20231 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO	CONFIRMATION NO
09 744,804	06/20/2001	Lea Eisenbach	EISENBACH 3	6094
i-144	7590 07 16 2002			
BROWDY AND NEIMARK, P.L.L.C.			EXAMINER	
624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	7
			DATE MAILED: 07/16/2002	/

Please find below and/or attached an Office communication concerning this application or proceeding.

,		Application No.	Applicant(s)			
Office Action Summary		09/744,804	EISENBACH ET AL.			
		Examiner	Art Unit			
		Misook Yu	1642			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address						
Period for Reply						
THE I - Externafter - If the - If NC - Failu - Any r	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Insions of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Period for reply specified above is less than thirty (30) days, a reply period for reply is specified above, the maximum statutory period were to reply within the set or extended period for reply will, by statute, eply received by the Office later than three months after the mailing and patent term adjustment. See 37 CFR 1.704(b).	66(a). In no event, however within the statutory minimu ill apply and will expire SIX cause the application to be	m of thirty (30) days will be considered timely.  (6) MONTHS from the mailing date of this communication.  come ABANDONED (35 U.S.C. § 133).			
1)[	Responsive to communication(s) filed on 20 J	<u>une 2001</u> .				
2a)	This action is <b>FINAL</b> . 2b) Thi	s action is non-fina	l.			
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
·	on of Claims					
·	4) Claim(s) 1-48 and 52 is/are pending in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
	Claim(s) is/are rejected.					
·	Claim(s) is/are objected to.	and/or election rea	uirom ont			
	Claim(s) <u>1-48</u> , and <u>52</u> are subject to restriction on Papers	and/or election req	uirement.			
9) The specification is objected to by the Examiner.						
-	The drawing(s) filed on is/are: a)□ accep		to by the Examiner.			
	Applicant may not request that any objection to the	e drawing(s) be held in	n abeyance. See 37 CFR 1.85(a).			
11) 🔲 -	The proposed drawing correction filed on	is: a) approved	b)  disapproved by the Examiner.			
If approved, corrected drawings are required in reply to this Office action.						
12)☐ The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received. 15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)						
2) Notic	te of References Cited (PTO-892) te of Draftsperson's Patent Drawing Review (PTO-948) mation Disclosure Statement(s) (PTO-1449) Paper No(s)	5) 🔲 No	terview Summary (PTO-413) Paper No(s)  btice of Informal Patent Application (PTO-152)  her:			

Art Unit: 1642

## **DETAILED ACTION**

## Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, linking claims (1, 19-34, and 44, and 52), and non-linking claims 2-4, drawn to peptides derived from Uroplakin.

Group II, linking claim 1 (1, 19-34, and 44, and 52) and non-linking claims 5 and 6, drawn to peptides derived from PSA.

Group III, linking claim (1, 19-34, and 44, and 52), and non-linking claims 7 and 8, drawn to peptides derived from PSMA.

Group IV, linking claims (1, 19-34, and 44, and 52), and non-linking claims 9 an 10, drawn to peptides derived from PAP.

Group V, linking claims (1, 19-34, and 44, and 52), and non-linking claims 11-14, drawn to peptides derived from Mucin.

Group VI, linking claims (1, 19-34, and 44, and 52), and non-linking claims 15 and 16, drawn to peptides derived from Lactadherin (BA-46).

Group VII, linking claims (1, 19-34, and 44, and 52), and non-linking claims 17 and 18, drawn to peptides derived from CRIPTO-1.

Groups **8-14**, claims 35 and 36, drawn to methods of prevention or cure of cancer or of metastasis by administering products of groups I-VII above.

Groups **15-21** claims 37-40, drawn to DNA encoding groups I-VII above, pharmaceutical composition comprising the DNA as the main active agent.

Applicant is requested to specify which SEQ ID encodes what peptides.

Art Unit: 1642

Groups **22-28** claims 41-43, drawn to vaccine comprising (groups I-VII above) antigen presenting cells.

Groups **29-35** claims 44-48, drawn to vaccine comprising (groups I-VII above) and a helper peptide as main active agents.

The inventions listed as Groups 1-35 do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: all of the peptides in the linking claims are from different human proteins with different molecular structurea and different biological activities, and are antigens for different tumors with different etiology and the different tumors respond differently to a given treatment. Further, PCT Rule 13.2 and 37 C.F.R. 1.475 define "special technical feature" as those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art." 37 C.F.R. 1.475(d) states that, if multiple products, processes of manufacture, or uses are claimed, the first mentioned in the claims will be considered as the main invention, along with each of the other categories related thereto. The main invention is a peptide from seven different tumor antigens. WO 94 20127A (15-09-1994, cited in PCT/IL99/00417) at Table 25 disclose peptide sequences with the same characteristics as claimed in claim 1; therefore, no special technical feature exists for claim 1 as defined by PCT Rule 13.2, because it does not define a contribution over the prior art. Since the main invention lacks a "special technical feature," unity of invention is lacking and restriction is proper.

Art Unit: 1642

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

- Different modifications in claims 23.
- Different carriers in claim 25 and 31.
- Different uses in claim 26 and 32.
- Different cancers listed in claim 27 and 33, claim 28 will be examined as it is
  drawn to the elected species of claim 27 and claim 34 will be examined as it is
  drawn to the elected species of claim 33.
- Different cell types listed in claims 42.
- Different method of presenting the antigens on the elected cells listed in claim 43.

If any group containing one or more of the above generic claim is elected,
Applicant is required, in reply to this action, to elect a single species (from each of the
generic claims) to which the claims shall be restricted if no generic claim is finally held
to be allowable. The reply must also identify the claims readable on the elected
species, including any claims subsequently added. An argument that a claim is
allowable or that all claims are generic is considered non-responsive unless
accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Art Unit: 1642

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Misook Yu whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Page 6

Application/Control Number: 09/744,804

Art Unit: 1642

Misook Yu July 9, 2002

> MARY E. MOSHER PRIMARY EXAMINER GROUP 1800

1600